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10/567,739	03/27/2006	Makoto Noami	2006_0106A	7704

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EXAMINER	
BUIE-HATCHER, NICOLE M	

ART UNIT	PAPER NUMBER
1796	

NOTIFICATION DATE	DELIVERY MODE
08/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/567,739	NOAMI ET AL.	
	Examiner	Art Unit	
	NICOLE M. BUIE-HATCHER	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14,22 and 28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,14,22 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20100723*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed 06/08/2010 has been entered. Claims 12, 14, and 22 remain pending. Claims 28-33 have been added.

Information Disclosure Statement

The information disclosure statement filed 02/10/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. No copy of the foreign patent document, JP 2003-509339 A has been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 28 and 31, each of these claims recites a composition comprising the polyvinyl alcohol copolymer, and a medicine, animal drug, agricultural chemical, fertilizer or

food component. However, it is unclear whether the composition is the coating composition as described in the instant specification where the polyvinylalcohol polymer coats or is the outer layer for a medicine, animal drug, agricultural chemical, fertilizer or food component as described in [0008] of the corresponding PG Pub **or** the coating or binder compositions comprising a medicine, animal drug, agricultural chemical, fertilizer, or food component as part of the film or binder. For the purpose of this Office Action, the above limitation will be treated as a polyvinylalcohol polymer as a coating or outerlayer for a medicine, animal drug, agricultural chemical, fertilizer or food component.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshi et al. (WO 02/17848, see English equivalent US 2003/0166763 A1).

Regarding claims 12 and 30, Hoshi et al. discloses in Synthesis Example 1, polyvinyl alcohol with SH end group (PVA-SH) wherein the degree of polymerization is 500, degree of hydrolysis 88%, with methacrylic acid (MAA) and methyl methacrylate. It is easily envisaged to substitute the methacrylic acid with acrylic acid as those are the more preferred monomers [0033]. In Table 1, for polymer compositions of E-1001, E-1002, and E-1003, the amount of

PVA-SH:MAA:MMA 75:5:20, 80:6:14, and 80:4:16, respectively. In each of these compositions, the ratio of partially hydrolyzed PVA-SH to polymerizable vinyl monomer is 3:1 for E-1001, 4:1 for E-1002, and 4:1 for E-1003. The ratio of MAA:MMA is 0.25 to 1 for E-1001, 0.43 to 1 for E-1002, and 0.25 to 1 for E-1003.

Regarding claim 31, the hard capsule for drugs for medical treatment, drugs/chemicals for animals or plants, and food [0048].

Claims 14, 22, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshi et al. (WO 02/17848, see English equivalent US 2003/0166763 A1).

Regarding claims 14 and 22, Hoshi et al. discloses in Synthesis Example 1, polyvinyl alcohol with SH end group (PVA-SH) wherein the degree of polymerization is 500, degree of hydrolysis 88%, with methacrylic acid (MAA) and methyl methacrylate. It is easily envisaged to substitute the methacrylic acid with acrylic acid as those are the more preferred monomers [0033]. In Table 1, in each of these compositions, the ratio of partially hydrolyzed PVA-SH to polymerizable vinyl monomer is 3:1 for E-1001, 4:1 for E-1002, and 4:1 for E-1003. The ratio of MAA:MMA is 0.25 to 1 for E-1001, 0.43 to 1 for E-1002, and 0.25 to 1 for E-1003.

Regarding claim 28, the hard capsule for drugs for medical treatment, drugs/chemicals for animals or plants, and food [0048].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 4,341,563) in view of Hoshi et al. (WO 02/17848, see English equivalent US 2003/0166763 A1).

Regarding claim 29, Kurihara et al. discloses a coating solution used to form a film comprising a water-soluble film base such as polyvinyl alcohol (C2/L61-C3/L2, C3/L42-56). Kurihara et al. is concerned with coating solid medicine (C1/L67-C2/L14).

However, Kurihara et al. does not disclose a copolymer consisting of a partially hydrolyzed polyvinyl alcohol and a polymerizable vinyl monomer consisting of acrylic acid or methyl methacrylate. Hoshi et al. discloses in Synthesis Example 1, polyvinyl alcohol with SH end group (PVA-SH) wherein the degree of polymerization is 500, degree of hydrolysis 88%, with methacrylic acid (MAA) and methyl methacrylate. It is easily envisaged to substitute the methacrylic acid with acrylic acid as those are the more preferred monomers [0033]. In Table 1,

in each of these compositions, the ratio of partially hydrolyzed PVA-SH to polymerizable vinyl monomer is 3:1 for E-1001, 4:1 for E-1002, and 4:1 for E-1003. The ratio of MAA:MMA is 0.25 to 1 for E-1001, 0.43 to 1 for E-1002, and 0.25 to 1 for E-1003. Kurihara et al. and Hoshi et al. are analogous art concerned with a similar technical difficulty, namely water-soluble polyvinyl alcohols used for medicine. It would have been obvious to one of ordinary skill in the art at the time of invention to substitute the polyvinyl alcohol per the teachings of Kurihara et al. with the polyvinyl alcohol per the teachings of Hoshi et al., and the motivation to do so would have been as Hoshi et al. suggests such polyvinyl alcohols have excellent stability and are water soluble [0003].

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 4,341,563) in view of Hoshi et al. (WO 02/17848, see English equivalent US 2003/0166763 A1).

Regarding claim 32, Kurihara et al. discloses a coating solution used to form a film comprising a water-soluble film base such as polyvinyl alcohol (C2/L61-C3/L2, C3/L42-56). Kurihara et al. is concerned with coating solid medicine (C1/L67-C2/L14).

However, Kurihara et al. does not disclose a copolymer consisting of a partially hydrolyzed polyvinyl alcohol and a polymerizable vinyl monomer consisting of acrylic acid or methyl methacrylate. Hoshi et al. discloses in Synthesis Example 1, polyvinyl alcohol with SH end group (PVA-SH) wherein the degree of polymerization is 500, degree of hydrolysis 88%, with methacrylic acid (MAA) and methyl methacrylate. It is easily envisaged to substitute the methacrylic acid with acrylic acid as those are the more preferred monomers [0033]. Kurihara et

al. and Hoshi et al. are analogous art concerned with a similar technical difficulty, namely water-soluble polyvinyl alcohols used for medicine. It would have been obvious to one of ordinary skill in the art at the time of invention to substitute the polyvinyl alcohol per the teachings of Kurihara et al. with the polyvinyl alcohol per the teachings of Hoshi et al., and the motivation to do so would have been as Hoshi et al. suggests such polyvinyl alcohols have excellent stability and are water soluble [0003].

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zeidler et al. (US 6,001,391) in view of Hoshi et al. (WO 02/17848, see English equivalent US 2003/0166763 A1).

Regarding claim 33, Zeidler et al. discloses a solid combination drug form 9C1/L6-10). The mixture comprises a binder, such as polyvinyl alcohol or copolymers of methyl methacrylate and acrylic acid (C2/L52-C3/L8).

However, Zeidler et al. does not disclose a copolymer consisting of a partially hydrolyzed polyvinyl alcohol and a polymerizable vinyl monomer consisting of acrylic acid or methyl methacrylate. Hoshi et al. discloses in Synthesis Example 1, polyvinyl alcohol with SH end group (PVA-SH) wherein the degree of polymerization is 500, degree of hydrolysis 88%, with methacrylic acid (MAA) and methyl methacrylate. It is easily envisaged to substitute the methacrylic acid with acrylic acid as those are the more preferred monomers [0033]. In Table 1, in each of these compositions, the ratio of partially hydrolyzed PVA-SH to polymerizable vinyl monomer is 3:1 for E-1001, 4:1 for E-1002, and 4:1 for E-1003. The ratio of MAA:MMA is 0.25 to 1 for E-1001, 0.43 to 1 for E-1002, and 0.25 to 1 for E-1003. Zeidler et al. and Hoshi et al. are analogous art concerned with a similar technical difficulty, namely water-soluble

polyvinyl alcohols used for medicine in a physiological medium. It would have been obvious to one of ordinary skill in the art at the time of invention to substitute the binder per the teachings of Zeidler et al. with the polyvinyl alcohol per the teachings of Hoshi et al., and the motivation to do so would have been as Hoshi et al. suggests such polyvinyl alcohols have excellent stability and are water soluble [0003].

Response to Arguments

Applicant's arguments with respect to claims 12, 14, and 22 have been considered but are moot in view of the new ground(s) of rejection. The following comment(s) apply:

A) The previous objection of claim 12, rejection of claims 14, 21, and 22 under 35 U.S.C. 102(a) as being anticipated by Hoshi et al., rejection of claim 16 under 35 U.S.C. 102(a) as being anticipated by Hoshi et al., rejection of claims 12, 14, 15, 21, and 22 under 35 U.S.C. 103(a) as being unpatentable over Angel et al., and rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Angel et al. have been withdrawn in light of Applicant's amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE M. BUIE-HATCHER whose telephone number is (571)270-3879. The examiner can normally be reached on Monday-Thursday with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. B./
Examiner, Art Unit 1796
8/6/2010

/David Wu/
Supervisory Patent Examiner, Art Unit 1796